Minutes of the meeting of the Confidentiality Advisory Group

21 January 2021 via Teleconference

Present:

Name	Present	Notes
Dr Tony Calland MBE	Yes	CAG Chair
Mr David Evans	Yes	CAG Member
Dr Liliane Field	Yes	CAG Member
Mr. Myer Glickman	Yes	CAG Member
Mr Tony Kane	Yes	CAG Member
Professor Jennifer Kurinczuk	Yes	CAG Member
Mr Andrew Melville	Yes	CAG Member
Ms Diana Robbins	Yes	CAG Member
Ms Clare Sanderson	Yes	CAG Alternative Vice-Chair

Also in attendance:

Name	Position (or reason for attending)
Ms Katy Cassidy	HRA Confidentiality Advisor

Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service
Dr Paul Mills	HRA Confidentiality Advice Service Manager

1. Introduction, apologies and declarations of interest

The Chair welcomed all members to the meeting. No apologies or written comments were received.

Any declarations of interest are detailed for each application below.

2. Support decisions

Secretary of State for Health & Social Care Decisions

The Department of Health & Social Care senior civil servant on behalf of the Secretary of State for Health & Social Care agreed with the advice provided by the CAG in relation to the **03 December 2020** meeting applications.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **03 December 2020** meeting applications.

3. Resubmissions

a. 21/CAG/0008 - Clinical Practice Research Datalink (CPRD) (Resubmission of ECC 5-05(a)/2012)

Context

Purpose of application

This item relates to an application that currently has support under reference ECC 5-05 (a)/2012. In the 2020 annual review, CAG had asked, due to the length of time since date of original support and need to ensure it reflected current practice, for updated application

documentation to be submitted. This application from the MHRA sets out the purpose of medical research to link data from numerous sources in order to establish a research database. The Clinical Practice Research Datalink (CPRD) service has been operating for in under Regulation 5 for a number of years and has established support under Regulation 5 for NHS Digital to act as a trusted third party in order to link data from numerous sources.

The CPRD is a government research service, jointly supported by the Medicines and Healthcare products Regulatory Agency (MHRA) and the National Institute for Health Research (NIHR) CPRD collects de-identified data from participating GP practices to establish the research database and to date includes over 50 million patient lives. Deidentified data is shared with research teams whose applications are reviewed by the CPRD's data governance review process. CPRD also provides other services to researchers, such as patient recruitment, support with interventional research and study planning/feasibility. It was noted that the broader activities undertaken by the CPRD were stated not to require Regulation 5 support.

However, about 75% of approved research protocols use linked data to provide more depth to the analysis. External data custodians (the organisations holding the data) provide NHS Digital with NHS number, gender, date of birth and postcode and a pseudonym. NHS Digital matches the identifiers to those provided by the GP system suppliers to generate a linker file (links GP system pseudonym with external dataset pseudonym). Deidentified data is then sent by the external data custodians to CPRD who link the data with the primary care data on pseudonyms alone. Some linkages are undertaken on a routine basis, where there is sufficient demand for them, whilst others may be undertaken on a study specific basis.

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	All patients within practices that have signed up to provide data to the CPRD (except for those patients that opt out).
Data sources	1. Data sources as identified in the master dataset

Identifiers required for linkage purposes	1. NHS number 2. Date of Birth 3. Postcode 4. Gender
Identifiers required for analysis purposes	1. Year of Birth 2. Date of Death 3. Gender 4. Occupation 5. Ethnicity 6. GP Practice Postcode and SHA region
Additional information	Note that month of birth is additionally provided for under 16s to support research into children and infants.

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Public interest

The CAG noted that this activity continued to fall within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006. The CAG understands that CPRD provides a well-established, valuable resource with the research using CPRD data being of high importance and in the public interest.

Response to Queries in 2020 Annual Review

Members reviewed the responses to the points raised in the 2020 annual review and accepted the majority of these. The CAG however requested further information on two areas; patient and public involvement and patient notification. These two points are discussed in more detail below.

Patient and Public Involvement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations and to help support public trust and confidence in the use of patient data without consent.

Within the 2020 annual review discussion, the CAG requested that in this submission the applicants should plan to undertake patient and public involvement proportionate to the scale and uses of the information. The CAG noted that the documentation had not fully engaged with this element at time of submission, and being mindful of published HRA guidance on public involvement, agreed that additional information would be requested so that appropriate patient involvement would be undertaken on a scale proportionate to the activity. . .

As such, members agreed that the applicants should, within one month from the date of the outcome letter, provide the CAG with a detailed protocol for patient and public involvement. The protocol should address immediate patient and public involvement to be undertaken and also detail an ongoing programme of patient and public involvement that CPRD will commit to. This will ensure demonstration of the continued public support of the CPRD and also help shape wider public trust and confidence on how their health information is used for research.

Within three months from the date of the outcome letter, relevant patient and public involvement should be undertaken with at least one patient and public involvement group and a detailed report provided to the CAG This involvement should include discussion around the acceptability of sharing confidential patient information from varying sources with NHS Digital to be able to undertake the linkages.

‘Patient Notification’ and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection and mechanism to respect that objection, where appropriate. This is known as ‘patient notification’. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

The applicants detailed in their response letter that work had been undertaken with Understanding Patient Data to update the website. Whilst noted by the CAG, it was considered by members that the public landing page on the CPRD website does not provide sufficient

transparency; this is detailed on a secondary page, but members felt that the public landing page should provide clear details on the use of confidential patient information without consent for linkages and how patients can opt out. This can be in a layered approach, with brief information detailing the use of confidential patient information without consent on the landing page and how to opt out linking to further detailed information on the secondary page. However, members agreed that transparency needs to be maintained to ensure public trust. This update should be undertaken within one month from the date of the outcome letter and reported to CAG.

Whilst agreeing that the poster needs to be clear, and that the poster provided is not factually incorrect members were of the view that the poster is not transparent regarding sharing of confidential patient information without consent. The CAG requests that, within one month from the date of this letter, the poster is updated to reflect that confidential patient information of some patients is used in order to link datasets.

The applicants should also consider, if they have not already done so, requesting practices to display this information on their website. In the current times, fewer patients are likely to visit a practice and a poster only will have less transparency than if it is also displayed on the practice website.

Research Protocol

Members noted that the research protocol provided was from 2012 and contains out of date references. For example, it refers to the use of free text which CAG understood is not covered within current scope of support. The applicants are asked to review and provide an up to date protocol to the CAG within one month from the date of the outcome letter.

Amendment

Alongside the provision of this revised application, the applicants also submitted an amendment. This amendment was to add the following datasets to the master dataset list:

- SGSS – Second Generation Surveillance System – from PHE
- CHESS – COVID-19 Hospitalisation in England Surveillance System – from PHE
- NPEx – National Pathology Exchange COVID-19 Pillar 2 test data – from NHS Digital
- HES-MSDS – Maternity Services Data Set – from NHS Digital
- NHSBSA – Medicines dispensed in primary care – from NHS Digital

- NCARDRS – National Congenital Anomaly and Rare Disease Registration Service – from PHE (CAG 10-02(d)/2015)
- NAAASP – NHS Abdominal Aortic Aneurysm Screening Programme data – from PHE

Members did not have any concerns about the proposed linkages in themselves but, in light of the requests made in relation to patient and public involvement and transparency, they agreed that the amendment could not currently be supported under Regulation 5 until the elements above have been met.

It is noted that the SGSS SARS-CoV-2 virology testing and CHESS data are already being linked, using the COPI Notice under Regulation 3(4) of the COPI Regulations 2002 as the legal basis and this can continue under this legal basis. However, other datasets could not be supported until the actions above have been resolved.

Further Discussion

Members noted that it may be useful to have a separate discussion with CPRD once these elements were addressed, and this would be considered once the revised application moved to full support.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending conditional support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. Within one month of the date of the outcome letter, provide evidence that the public landing page of the CPRD website contains details about the use of confidential patient information without consent, and a mechanism to opt out, linking to a secondary page for further details.

2. Within one month to provide an updated poster that adequately refers to the use of confidential patient information without consent.

3. Within one month to provide an updated protocol which reflects the current research processes of CPRD.

4. Within one month to provide a detailed protocol for both initial and ongoing patient and public involvement on the use of confidential patient information without consent for the purposes of linking datasets for the CPRD service.

5. Within three months to provide a report on the resulting initial patient and public involvement that has been undertaken.

6. Following submission of the initial patient and public involvement, a meeting will be arranged between members of the CAG and CPRD.

7. Regulation 5 support for the specific datasets to be added to the master dataset list for linkage by NHS Digital, as detailed in the amendment form, is not supported until satisfactory resolution of the above points. However, it is noted that the SGSS SARS-CoV-2 virology testing and CHESS data will continue to flow with the COPI notice as the legal basis.

8. Favourable opinion from REC **Received**

9. Continual achievement of 'Standards Met' in relation to the relevant DSPT submission (or any future security assurance changes) for the duration of support. Evidence to be provided (through NHS Digital confirmation they have reviewed and confirmed the DSPT submission as standards met' for the duration of support, and at time of each annual review. **The 19/20 DPST submission NHS Digital has been confirmed as 'standards met'.**

As the above conditions have been accepted or met, the register of approved applications on the HRA website has been updated with this information.

Declarations of Interest

There were no declarations of interest.

4. Response to Conditions of Annual Review

a. CAG 10-02(d)/2015 - National Congenital Anomaly and Rare Disease Registration Service (NCARDRS)

The CAG reviewed the applicant's response to the conditions of their 2020 annual review and made the below comments;

1. The CAG noted and accepted the progress made so far.
2. Members recognised that the next annual review is due in April 2021 and asked that more detailed information was provided about the ongoing review of materials and further progress made in the 2021 annual review.
3. The CAG recommended that links to relevant support groups, who could be consulted on the materials, were made.
4. The CAG noted that the HRA had recently published guidance on PPI and how this can be conducted during Covid-19, which is available here https://www.hra.nhs.uk/planning-and-improving-research/best-practice/public-involvement/

Declarations of Interest

There were no declarations of interest.

5. New applications – Research

a. 21/CAG/0001 – Optimum Patient Care Research Database (OPCRD)

Context

Purpose of application

This application from Optimum Patient Care (OPC) Ltd set out the purpose of creating a real-world, longitudinal research database that provides anonymised data to support scientific, medical, public health and exploratory research.

The OPC database holds de-identified data provided from participating GP practices. Data collection for OPCRD is conducted by Optimum Patient Care Limited (OPC), a not-for-profit social enterprise that provides quality improvement programmes for chronic conditions and research support services to GP practices across the UK. OPC quality improvement programmes and research support services are provided at no cost to participating GP practices under a service agreement.

As part of the service agreement, GP practices agree to contribute de-identified patient data to OPCRD for quality improvement and for research purposes. This includes de-identified longitudinal primary care patient data (derived from both electronic health records (EHR) data and from patient questionnaires delivered as part of quality improvement) and data linked from other health-related datasets e.g. secondary care data. The population base for OPCRD is all patients at contributing GP practices, excluding patients who have opted-out or refused consent for data sharing for care planning (quality improvement) or for research purposes. Data recorded or coded as "Confidential" in patient EHR and sensitive special category data which are not relevant for quality improvement or research, such as sexually transmitted diseases (STDs), termination of pregnancy, fertility treatment, marital status, convictions/imprisonments, physical/psychological/sexual abuse, etc. are not collected by OPC or for OPCRD.

Data contributed to OPCRD enables research into all chronic conditions in primary care. OPCRD has received data contributions from over 750 GP practices and currently holds de-identified data for approximately 9.6 million patients or data subjects. Over the last calendar year of 2019, the OPCRD has received data contributions from over 320 GP practices, accounting for over 3.6 million non-identifiable patient records. Anonymised data only is supplied to researchers for use in ethically approved scientific and public health research. All research conducted using the OPC database must also be approved by the Anonymised Data Ethics and Protocols Transparency committee (ADEPT). Proceeds from OPCRD data access fees and detailed feasibility assessments are re-invested into OPC services for the continued free provision of patient quality improvement programmes and research support services for contributing GP practices.

OPCRD receives pseudonymised de-identified electronic health records data and questionnaire data of patients from participating GP practices. This may include de-identified questionnaire data for any condition or disease. OPCRD may also receive anonymised linked data from other health-related datasets and registries for patients from consented contributing GP practices. This may include Hospital Episode Statistics (HES), Scottish Morbidity Record (SMR), Patient Episode Database for Wales (PEDW), Northern Ireland Hospital Statistics (NIHS).

The applicants are seeking support under s251 for the disclosure of confidential patient information from participating GP practices to the Harvey Walsh Secure Portal. Harvey Walsh will then collect all patient identifiers and Study IDs received from the participating GP practices and combine them into one file. Harvey Walsh will then transfer the patient identifiers and Study ID to NHS Digital via the Health and Social Care Network (HSCN). NHS Digital will match the dataset to HES and return de-identified HES data, with Study IDs, to Harvey Walsh via the secure HSCN. Harvey Walsh will use the Study IDs to link the de-identified GP electronic health records data, received from OPCRD, with the de-identified HES data to create the linked OPCRD-HES dataset, which is stored securely on OPCRD-NEXUS. No

patient identifiable data will be held in OPCRD or OPCRD-NEXUS. The applicants will request linkages from NHS Digital on a quarterly or six-monthly basis.

The applicants acknowledged that linkages to SMR and NIHS are outside the remit of Regulation 5 ('s251' support). Support for linkage to PEDW data was not sought within this application.

A recommendation for class 1, 2, 3, 4, 5, and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	All patients registered at contributing GP practices, unless patients have objected to sharing of their data for use in research or care planning.
Data sources	1. Electronic patient information provided by participating GP practices 2. HES datasets (HES Admitted Patient Care, HES Outpatient Care, HES Critical Care, HES Accident and Emergency (A&E), HES Emergency Care Data Set (ECDS) and HES Civil Registry (Deaths)) held at NHS Digital
Identifiers required for linkage purposes	1. NHS number 2. Date of birth 3. Postcode – unit level
Identifiers required for analysis purposes	No identifiers will be retained for analysis

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006. The CAG agreed that the application had a medical purpose and was in the public interest.

Data flows

Harvey Walsh will collect all patient identifiers and Study IDs received from the participating GP practices and combine them into one file. Harvey Walsh will then transfer the patient identifiers and Study ID to NHS Digital via the Health and Social Care Network (HSCN). NHS Digital will match the dataset to HES and return de-identified HES data, with Study IDs, to Harvey Walsh via the secure HSCN. Harvey Walsh will use the Study IDs to link the de-identified GP electronic health records data, received from OPCRD, with the de-identified HES data to create the linked OPCRD-HES dataset, which is stored securely on OPCRD-NEXUS.

The CAG requested reassurance that the two databases held by Harvey Walsh, one containing identifiable data and the other containing de-identified data, would be held completely separately and could not come into contact with each other to allow accidental or deliberate re-identification; and a description of the measures providing this assurance.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available.

- **Feasibility of consent**

The applicants explained that over 2 million anonymised patient records are contributed to OPCRD each year, and it is not practicable to consent this number of patients. The CAG agreed that consent was not feasible.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to link confidential patient information supplied by GPs to the HES datasets at NHS Digital. This cannot be undertaken in any other way.

On questioning whether GPs can send confidential patient information to NHS Digital directly, the applicants advised that they will consider this with NHS Digital with future data flows. The CAG agreed that this change to the data flow needed to be explored by the applicants and reported to the CAG at the first annual review. If the data flow could not be revised, a justification for this will need to be provided.

- **Justification of identifiers**

The CAG requested that further clarification was required on the identifiers that will be retained in the OPCRD-HES dataset, specifically whether patients' year of birth, date of death, GP registration, occupation, gender, ethnicity, district postcode or unit level postcode will be retained. The dataset was described as being anonymised, however if some or all of the identifiers listed above were included, then the dataset would contain items of confidential patient information.

- **De-identification of data**

The CAG noted that data already collected was being held on the basis that it was sufficiently anonymised, and members agreed that it needed to be confirmed that the anonymisation process was robust. Members asked that information was provided on the process of redacting free text, including the success/failure rate of the method used, and how the applicants have ensured the efficacy of the two-stage process.

During stage 2 of the redaction, a 'global dictionary of known associations' will be consulted. Members requested further details on the associations that would be removed, e.g. will the names of organisations such as NHS Trusts and GP practices be removed.

The CAG asked that the applicant confirm that data being transferred outside the UK was sufficiently anonymised and requested details on how this was assured.

- **'Patient Notification' and mechanism for managing dissent**

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

A poster was provided for GPs to display in their practices. This advised patients to contact their GP practice or the National Data Opt-Out service and provided a link to the National Data Opt-Out. The applicants advised that they would also encourage GP practices to include information about the OPCRD on their practice websites.

A privacy notice was also displayed on the OPC website. It was noted that this did not meet the requirements of the patient notification expected by the CAG. The CAG asked that the privacy notice was used as a basis for information, written in plain English, that could be displayed on relevant websites, social media, etc, to promote the study.

The applicant advised that any patient data that included a record (Read code or SNOMED CT code) which indicated that the patient had opted out of or dissented from data sharing for planning or for research would be excluded from the data collection for quality improvement or for research.

Patients in England were also able to opt-out of their GP sharing their data for planning and research by expressing their wishes through the National Data Opt-Out Scheme. OPC, together with the GP clinical system providers, support GP practices in adhering to the policy; data is checked with the NHS central checking system for national data opt-outs before it is extracted.

The OPCRD holds no patient identifiable data, therefore the applicant advised that it is not possible to identify patients who dissented after their data was sent to OPCRD, and their data cannot be removed. However, patients who do request to opt out will be excluded from future

data collections. GP practices will be encouraged to update OPC with any patients who dissent so that they can be excluded from subsequent data collection.

The CAG noted that the answer given to the CAT advice form implied that the local practice opt out process would only be in place until the National Data Opt-Out deadline of 31 March 2021. After this time only the National Data Opt-Out will be applied. The CAG recognised the difficulty in promoting and facilitating a project-specific process, however members agreed that a project-specific opt-out still needed to be included.

The CAG noted that the National Data Opt-Out only applied in England. If any confidential patient information generated within Wales would be processed, then a local opt-out needed to be in place for patients in Wales. Members suggested that the Type 1 opt-out continued to be applied for Welsh and English patients

The CAG agreed that the poster and website information needed to include information on local opt-out. Members also suggested that examples of the work that the dataset would be used for were included.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

It appears that no specific patient and public involvement has been undertaken on the use of confidential patient information without consent. On questioning further, the applicants explained that OPC were in the process of establishing a dedicated patient and public involvement group for OPCRD-NEXUS to specifically look at the unconsented activity for data linkage, and to also support the ethical approval of studies. OPC included lay members on the steering committee, involving them in development and strategic decisions around OPC projects. Besides the development phase, a lay member is also involved in the approval process of research performed within OPCRD.

As part of the ADEPT committee, which also included independent clinical experts and scientists with expertise in statistics, epidemiological experience and/or EHR-based research, a lay member would be able express the public view in research approval discussions and

decisions. Lay members, as part of an associated patient advisory group, reviewed the OPCRD-NEXUS poster and other fair processing materials.

The CAG agreed that it was best practice to include at least two lay members to be in each committee.

The CAG agreed that specific patient and public involvement has not yet been undertaken on the use of confidential patient information without consent. An outline plan for such consultation needed to be provided in the applicant's response to the provisional outcome, and feedback from the patient and public involvement provided at the first annual review.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Health Research Authority that the activity be provisionally supported. However, further information and actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

In order to complete the processing of this application, the applicant was required to respond back to all of the request for further information, and actions required to meet the specific conditions of support where indicated, within one month.

Request for further information

1. Provide reassurance that the two databases held by the Harvey Walsh Secure Portal, one containing identifiable data and the other containing de-identified data, would be held completely separately and could not come into contact with each other to allow accidental or deliberate re-identification; and a description of the measures providing this assurance.

2. Provide further clarification on the identifiers that will be retained, specifically whether patients' year of birth, date of death, GP registration, occupation, gender, ethnicity, district postcode or unit level postcode will be retained.

3. Provide further details on the process of redacting free text, including the success/failure rate of the method used, and how the applicants have ensured the efficiency of the two-stage process.

4. Provide further details on the associations that will be redacted from free text following consultation of the 'global dictionary of known associations', e.g. will the names of organisations such as NHS Trusts and GP practices be removed.

5. Confirm that data transferred outside the UK will be sufficiently anonymised and provide details on how this will be assured.

6. Confirm that at least two lay members will be included on the steering committee and ADEPT committee.

7. Undertake patient and public involvement around the specific issue of the use of confidential patient information without consent. An outline plan needs to be provided in the response to the provisional outcome and feedback from the patient and public involvement provided at the first annual review.

Once received, the information will be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory and the outstanding actions listed in the specific conditions of support are met, a final support outcome will be issued.

Specific conditions of support (Provisional)

The following sets out the provisional specific conditions of support. These may change in the final outcome letter depending on the responses to queries.

1. The potential change to the data flow, so that GPs can send confidential patient information to NHS Digital directly, needs to be explored by the applicants and reported to the CAG at the first annual review. If the data flow cannot be revised, a justification for why this could not be given will need to be provided.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 06 July 2020**

3. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information.

- **Confirmed: NHS Digital and Harvey Walsh Ltd (by check of the NHS Digital DSPT spreadsheet on 25 January 2021) have confirmed 'Standards Met' grade on DSPT 2019/20.**

- **Participant GP practices – Due to the number of participating sites where confidential patient information will be accessed, individual DSPT submissions are not required for the purpose of the application. Support is recommended on the basis that the applicant ensures the required security standards are in place at each site prior to any processing of confidential patient information with support under the Regulations.**

Declarations of Interest

There were no declarations of interest.

b. 21/CAG/0006 - Effect of Statins in Community Acquired Pneumonia

Context

Purpose of application

This application from the Queen Elizabeth Hospital Kings Lynn NHS Trust sets out the purpose of medical research that seeks to determine whether taking a statin reduces the 30-day mortality and the length of hospital stay after admission for patients aged 65 years and over with community acquired pneumonia.

Statin drugs are used for primary and secondary prevention of vascular disease. A growing body of evidence suggests that statins may have intracellular anti-inflammatory effects that may confer survival benefits in the context of acute infection. In a Quality Improvement Project, conducted into deprescribing practices, statins were found to reduce 30-day mortality, even in those who were, on average, older and suffering more severe disease. However, the number of patients involved in this project was too small to measure significance. The applicants are seeking to undertake a retrospective cohort study to measure any difference in the 30-day mortality and length of stay for patients aged 65 years and over who were admitted to hospital with Community Acquired Pneumonia.

A list of eligible patients will be provided by the Clinical Coding Department within Queen Elizabeth Hospital Kings Lynn NHS Trust. Patients' Electronic Discharge Letter, held on the Trust ICE system, will be examined, from which the applicants will record the date of birth, admission date, discharge date, CURB-65 score, statin type, doses or if statins were discontinued and date of death if applicable.

A recommendation for class 1, 5 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	1500 male and female patients aged 65 years and over who were admitted to Queen Elizabeth Hospital Kings Lynn NHS Trust with Community Acquired Pneumonia
Data sources	1. Electronic records held at Queen Elizabeth Hospital Kings Lynn NHS Trust
Identifiers required for linkage purposes	1. NHS number 2. Hospital ID number 3. Date of birth 4. Date of death 5. Gender
Identifiers required for analysis purposes	1. Gender

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006. The CAG agreed that the application had a medical purpose and was in the public interest.

Scope

The CAG noted that in section 9-2 of the CAG application form, the applicant explained that "If such an effect is shown in this population, we will contact our colleagues in Primary Care to establish the course length in statin use before the measured effect is established." Members requested that further details on how any linkages to primary care data would be undertaken were provided, including whether support was sought for these linkages in this application or if a future application or amendment would be made.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available.

- **Feasibility of consent**

The applicants state that the number of patients involved means that consent is not feasible. Only 1500 patients were involved, however the second reason given, that the proposed data collection was retrospective, and patients may have died or moved away, is a stronger reason for not consenting.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to identify suitable patients and link to their electronic discharge letter, and to check for duplications. The CAG noted this could not be done in any other way.

Cohort

The CAG noted some inconsistencies in the references to the time frame for inclusion in the study. The applicant was asked to confirm if patients admitted to Queen Elizabeth Hospital Kings Lynn NHS Trust with Community Acquired Pneumonia between January 2018 and January 2020 would be included, or if different dates would be used.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

The applicants will display posters in outpatient clinics, pharmacies and other relevant areas. This will include the project leads email address for patients to contact with any queries and to request dissent.

The CAG noted that the poster did not explain the opt-out process and asked that the poster was revised to explain how patients could dissent from the inclusion of their data in the research. The poster also referred to anonymised data and members asked that this was revised to explain that access to confidential patient information was required in order to extract the anonymised dataset. If any items of confidential patient information would be retained, for example, to facilitate linkages to primary care data, this would also need to be explained.

The CAG noted the difficulty in promoting the study and asked that the applicant explore additional ways of disseminating information about the study, including social media, via appropriate websites, etc, and report back to the CAG.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

The CAG advised that patient and public involvement needed to be carried out. Guidance is available on the HRA website. A plan for patient and public involvement needs to be provided in the applicants' response to the provisional outcome. Patient and public involvement then needs to be undertaken and feedback provided within six months of the issue of the fully supported outcome.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Health Research Authority that the activity be provisionally supported. However, further information and actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

In order to complete the processing of this application, the applicant was required to respond back to all of the request for further information, and actions required to meet the specific conditions of support where indicated, within one month.

Request for further information

1. Provide further details on how any linkages to primary care data would be undertaken, including whether support was sought for these linkages in this application or if a future application or amendment would be made.

2. Advise if patients admitted to Queen Elizabeth Hospital Kings Lynn NHS Trust with Community Acquired Pneumonia between January 2018 and January 2020 would be included, or if different dates for inclusion would be used.

3. The poster needs to be revised as follows:

a. The poster needs to explain how patients can dissent from the inclusion of their data in the research.

b. The poster needs to explain that access to confidential patient information is required in order to extract the anonymised dataset.

c. If any items of confidential patient information will be retained, this needs to be explained.

4. A plan on how patient and public involvement is to be undertaken needs to be provided in the response to the provisional outcome.

Once received, the information will be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory and the outstanding actions listed in the specific conditions of support are met, a final support outcome will be issued.

Specific conditions of support (Provisional)

The following sets out the provisional specific conditions of support. These may change in the final outcome letter depending on the responses to queries.

1. Feedback on the patient and public involvement undertaken is to be provided within six months of the conditionally supported outcome being issued.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 11 September 2020.**

3. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information.

- DSPT **pending** for Queen Elizabeth Hospital Kings Lynn NHS Trust

Declarations of Interest

There were no declarations of interest.

6. New applications – Non-Research

a. 20/CAG/0007 - National Neonatal Audit Programme (NNAP) data flow

Context

Purpose of application

This application from the Royal College of Paediatrics and Child Health (RCPCH) sets out the purpose of an audit programme, to assess whether babies admitted to neonatal units in England and Wales receive consistent high-quality care and to identify areas for service and quality improvement in relation to the delivery and outcomes of neonatal care.

The National Neonatal Audit Programme (NNAP) was established in 2006 and has, until now, been delivered by the RCPCH and is commissioned to do so by the Healthcare Quality Improvement Partnership (HQIP) as part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP). The NNAP assesses whether babies admitted to neonatal units in England and Wales receive consistent high-quality care and identifies areas for service and quality improvement in relation to the delivery and outcomes of neonatal care as measured by adherence to a set of agreed professional guidelines and standards. Currently, for the 1 April 2017 to 31 March 2021 NNAP contract period, neonatal units use identical (BadgerNet) software to route clinical data via Clevermed Ltd into the National Neonatal Research Database (NNRD) dataset maintained at Imperial College by the Neonatal Data Analysis Unit (NDAU), (CAG reference: ECC 8-05(f) 2010). NNAP data is a sub-set of the wider NNRD and the NDAU processes NNAP data on behalf of the RCPCH to whom it provides quarterly and annual aggregated and anonymised reports.

The NNAP is not run or delivered by the National Neonatal Research Database (NNRD), as the Neonatal Data Analysis Unit (NDAU) within Imperial College is sub-contracted by the RCPCH to undertake data analysis for the NNAP and it does this by processing NNAP-related data within the NNRD using the legal basis given under CAG reference ECC 8-05(f)2010. The applicants are now seeking support under Regulation 5 of the COPI Regulations for the NNAP, so that NNAP will have its own support and will no longer come under ECC 8-05(f)2010.

Participating Neonatal units will input confidential patient information into the BadgerNet system on all babies admitted to all NHS neonatal units in England and Wales associated with a delivery unit, including special care units (SCUs), local neonatal units (LNUs) and neonatal intensive care units (NICUs). Data entered into BadgerNet is stored on servers within the Clevermed Microsoft Azure environment, accessible only via the HSCN NHS Network. A dedicated NNAP SQL Server Database will be created by Clevermed within its Azure environment for the sole purpose of hosting the national NNAP dataset extracted from the live BadgerNet system. Data for each neonatal care episode will be added to the dedicated NNAP SQL Server Database thirty days after the date of the baby's discharge from neonatal care. After this date any changes by users to that raw BadgerNet record will be synchronised to the dedicated NNAP database so that it always reflects the current raw BadgerNet care record. The NNAP Database within the Clevermed Azure environment can then be synchronised to a "mirror" instance of a NNAP SQL Server Database located on an entirely separate RCPCH Azure hosting infrastructure. Appropriately trained and approved RCPCH-based NNAP project staff will be able to work with data within the NNAP database within the RCPCH Azure environment only and produce monthly, quarterly or whole-year analysis and reporting. A pseudonymised version of the NNAP data will be created within the RCPCH Azure environment and it is this pseudonymised version of the data that the NNAP project team will work with. The applicant confirmed that confidential patient information is put into the BadgerNet system by participating trusts as part of routine care and input into BadgerNet is outside the scope of the s251 support sought.

A recommendation for class 1, 5 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	The following inclusion criteria apply to all NNAP measures: • Babies who were admitted for neonatal care • Babies who had care provided by an NNAP-registered NHS neonatal unit • Babies whose parents or carers have not opted them out of secondary use of their data
Data sources	1. Confidential patient information entered by participating neonatal units into BadgerNet

Identifiers required for linkage purposes	1. NHS Number of baby 2. NHS number of mother
Identifiers required for analysis purposes	1. Date and time of baby's admission 2. Date of time of baby's discharge 3. Date and time of baby's birth 4. Baby's date of death 5. Mother's date of birth 6. Mother's ethnicity 7. Gender of baby 8. Postcode of mother's usual address

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Secretary of State for Health and Social Care.

Public interest

The CAG noted that this activity fell within the definition of the management of health and social care services and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006. The CAG agreed that the application had a medical purpose and was in the public interest.

Scope

The CAG noted that the main NNRD dataset would continue under its own support and the NNAP would now be a separate database operating under separate support and the NDAU would no longer be involved. Members queried what would be done with the historical datasets used for the NNAP, which had been collected under the NNRD support and held by NDAU.

The data flow diagram suggested that support was required for the flow of confidential patient information from BadgerNet to CleverMed, however this data flow appeared to be for the purpose of direct care. The CAG asked the applicant to confirm that this was the case.

The CAG understood that support was needed for the disclosure of confidential patient information from CleverMed to the NNAP sub-dataset, held within CleverMed, which was then used to create the mirror dataset at RCPCH. The mirror dataset will then be used to create a pseudonymised dataset, held within RCPCH. Members asked that the applicant confirm this.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available.

- **Feasibility of consent**

90,000 babies admitted to NHS neonatal units in England and Wales each year. The applicants noted that it would be burdensome to parents and impracticable for staff to seek consent from each parent for every admission to neonatal care. The applicants noted that admission to neonatal care was a distressing time for parents and that it would be potentially upsetting to approach parents for consent or assent. The CAG agreed that consent was not feasible.

- **Use of anonymised/pseudonymised data**

A pseudonymised version of the NNAP data will be created within the RCPCH Azure environment and it is this pseudonymised version of the data that the NNAP project team will work with.

The CAG requested clarification on whether staff from CleverMed or staff from RCPCH will access the identifiable mirror dataset in order to remove identifiers to create the pseudonymised dataset. If the pseudonymisation process was carried out by RCPCH staff, the CAG asked if it was possible for CleverMed staff to undertake this process instead, reducing the processing of confidential patient information outside of the direct care team. If it was not possible for CleverMed staff to undertake the process, an explanation as to why this was not possible needed to be given.

If the pseudonymisation process would be undertaken by RCPCH staff, the CAG requested details on what would be done with the identifiers removed. The application advised that the identifiers would be retained for one year to check for duplicate records, and members asked if this was correct.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

The NNAP Project Team within the RCPCH have produced a number of materials which are used to inform the parents of the use of both baby and mother's data for the purpose of the NNAP. This includes a "Your baby's care" booklet (Appendix C), which are sent to each participating neonatal unit. The NNAP data protection impact assessment and Privacy Notice (Appendix H) are also made available on the project website.

Any notifications of dissent made to NNAP will be forwarded by the NNAP project team to the relevant Health Board/Trust, who are the data controller for the patient record and are able to do appropriate verification checks.

Participating Health Boards and Trusts are responsible for applying the national opt out process and opt out functions are built in to the BadgerNet systems within neonatal units.

The CAG reviewed the notification materials and noted that they did not appear to have been created for the purpose of this application specifically. The "Your baby's care booklet" directed parents/carers to the NNAP website for information on how to dissent. Members noted that it could not be assumed that parents/carers of a child on a neonatal unit would have access to the internet and agreed that written materials that described how to dissent were created. The CAG also noted that only the privacy notice and information on opt-out was available online and asked that further details were given online about the NNAP, specifically the processing of confidential patient information required.

The CAG noted that many neonatal units currently did not allow leaflets to be used, due to issues around infection control, but that use of posters was possible. A poster, promoting the application, was to be produced and the application referred to patient and public involvement engagement being undertaken around its design. Members agreed that this poster needed to be reviewed by the CAG before support could be recommended.

Further details on how the “Your baby’s care” booklet would be disseminated were requested.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

The applicant advised that BLISS has been involved in the NNAP for a number of years as a key stake holder and is represented on the Project Board. BLISS assisted in the recruitment of two parent representatives onto the NNAP Project Board and methodology and dataset group in 2015 and ensure that they are continually empowered to have a voice and influence the work of the audit.

The parent representatives on the Project Board have helped to ensure that the NNAP “Your Baby’s Care” booklet is a valued resource which sets out the aims and results of the NNAP clearly and concisely for parents and carers and prompts conversations about the audit between parents and carers and staff within neonatal units.

The CAG noted the patient and public involvement that had been conducted in previous years. Members asked that letters of support from BLISS and the parent representatives were provided, evidencing that they were supportive of the project. The CAG also asked that the applicant confirm whether the processing of confidential patient information as required in this application had been specifically discussed during patient and public involvement.

Exit strategy

The CAG noted that confidential patient information would be retained for the initial one-year duration of the contract and that amendments would be submitted to extend this, if needed.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Secretary of State for Health and Social Care that the activity be provisionally supported. However, further information and actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

In order to complete the processing of this application, the applicant was required to respond back to all of the request for further information, and actions required to meet the specific conditions of support where indicated, within one month.

Request for further information

1. Confirm that support is needed for the disclosure of confidential patient information from CleverMed to the NNAP sub-dataset, held within CleverMed, which will then used to create the mirror dataset at RCPCH. The mirror dataset will then be used to create a pseudonymised dataset, held within RCPCH.

2. Clarify what will be done with the historical datasets, collected for the NNAP under the support for NNRD and held by the NDAU.

3. Further details on the pseudonymisation process is required;

    a. Clarify whether staff from CleverMed or staff from RCPCH will access the identifiable mirror dataset in order to remove identifiers to create the pseudonymised dataset.
    b. If the pseudonymisation process is carried out by RCPCH staff, explain if it is possible for CleverMed staff to undertake this process instead. If it is not possible for CleverMed staff to undertake the process, provide an explanation on why this cannot be done.
    c. If the pseudonymisation process will be undertaken by RCPCH staff, the provide details on what will be with the identifiers removed. The application advised that the identifiers would be retained for one year to check for duplicate records. Please confirm if this is correct.

4. The following changes to the patient notification and dissent mechanism were requested;

a. Written materials, such as a poster, need to be created and provided to the CAG for review.
b. Details on the NNAP, including the processing of confidential patient information required for the purpose of the audit and how parents/carers can dissent to the inclusion of their child's data, need to be made available online.
c. Further details on how the "Your baby's care" booklet will be disseminated need to be provided.

5. Further information on patient and public involvement needs to be provided:

a. Please provide letters of support from BLISS and the parent representative, evidencing that they are supportive of the project.
b. Please also confirm whether the processing of confidential patient information as required in this application has been specifically discussed during patient and public involvement, and provide feedback from these discussions.

Once received, the information will be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory and the outstanding actions listed in the specific conditions of support are met, a final support outcome will be issued.

Specific conditions of support (Provisional)

The following sets out the provisional specific conditions of support. These may change in the final outcome letter depending on the responses to queries.

1. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information.

- **Confirmed: Royal College of Paediatrics and Child Health (by check of the NHS Digital DSPT tracker on 26 January 2021) has a confirmed 'Standards Met' grade on DSPT 2019/20)**
- **DSPT pending for CleverMed Ltd and Microsoft UK Azure Server Hosting**

Declarations of Interest

There were no declarations of interest.

7. Office Report

The office report was received by all Members.

8. Any other business

No other business was raised.

The Chair thanked Members for their attendance and the meeting was closed.

Signed – Chair	Date
Signed – Confidentiality Advice Team	Date